NDA 50-443/S-029

Bristol-Myers Squibb Company
P.O. Box4000
Princeton, NJ 08543-4000
Attention: Joseph A. Linkewich, Pharm.D.
Director, U.S. Regulatory Liaison
Worldwide Regulatory Affairs

OCT 20 1999

Dear Dr. Linkewich:

Please refer to your supplemental new drug application dated August 31, 1999, received September 3, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Blenoxane® (bleomycin sulfate for injection, USP). We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We note that this supplement was submitted as a 'Special Supplement - Changes Being Effected' under 21 CFR 314.70(c) with final printed labeling.

This supplemental new drug application provides a revised package insert with the addition of the following statement to the **ADVERSE REACTIONS**, Integument and Mucous Membranes section (new second paragraph): "Scleroderma-like skin changes have also been reported as part of postmarketing surveillance." Your submission stated the package insert will be used in production no later than December 1, 1999.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted August 31, 1999). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MED WATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Leslie Vaccari, Project Manager, at (301) 594-5784.

Sincerely,

Richard Pazdur, M.D.
Division Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research